REMARKS/ARGUMENTS

Status of Claims

Claims 8, 9, and 17 have been previously canceled.

Claims 18-20 have been previously withdrawn.

Thus, claims 1-7 and 10-16 are currently pending in this application.

Applicants hereby request further examination and reconsideration of the presently claimed application.

Claim Rejections – 35 U.S.C. § 103

Claims 1-7 and 10-16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wain, et al., WO 00/45795 (hereinafter "*Wain*") in view of Foldvari, PSTT, 2000, 3(12), 417-425 (hereinafter "*Foldvari*"). Claims 2-7 and 10-16 depend from independent claim 1. Thus, claims 2-7 and 10-16 stand or fall on the application of the combination of *Wain* and *Foldvari* to independent claim 1. As noted by the United States Supreme Court in *Graham v. John Deere Co. of Kansas City*, an obviousness determination begins with a finding that **"the prior art as a whole in one form or another contains all" of the elements of the claimed invention**. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 22 (U.S. 1966). Applicants respectfully submit that the combination of *Wain* and *Foldvari* does not contain all of the elements of independent claim 1.

Particularly, Applicants submit that the combination of *Wain* and *Foldvari* does not disclose the limitation that the formulation comprises ***at least about 70% by weight ethanol***. Independent claim 1 recites:

> A transdermal spray formulation comprising:
> a) a pharmaceutically active agent;
> b) 0.1% to about 5.0% by weight VP/VA copolymer;
> c) **at least about 70% by weight ethanol**; and

> d) optionally a penetration enhancer, which, if present, is present in an amount of 0.01% to 5.0% by weight of the composition.

See supra, emphasis added. As shown above, claim 1 recites the limitation that the formulation comprises ***at least about 70% by weight ethanol***. The Final Office Action relies upon *Wain* to disclose this limitation as follows:

> Claim 3 states that the composition may comprise up to 90% of the vehicle, where claim 18 defines the vehicles as including absolute alcohol (i.e. ethanol). Therefore, one would have been motivated to formulate a composition comprising up to 90% ethanol.

See Office Action at 2. For the reasons discussed below, Applicants respectfully submit that *Wain* cannot properly be cited as teaching this limitation.

First, Applicants respectfully submit the Final Office Action fails to consider *Wain* in its entirety. MPEP § 2141.02.VI states: "**A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.** *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)." *Wain* specifically recites:

> ... the compositions of the present invention **will contain at most about 60% ethanol, and usually much less**.

See Wain at page 3 (emphasis added). Thus, *Wain* discloses the use of ***at most about 60% ethanol*** and, as such, ***teaches away*** from a composition comprising ***at least about 70% by weight ethanol***, as recited in claim 1. *Id.*

Second, Applicants respectfully submit that one of skill in the art reading *Wain* in its entirety would not understand *Wain* to disclose ***at least about 70% by weight ethanol***. As shown above, the Final Office Action cites claims 3 and 18 of *Wain* in combination as disclosing this limitation. However, one of skill in the art would not understand claims 3 and 18 to disclose ***at***

least about 70% by weight ethanol. Rather, claims 3 and 18 disclose that ***a vehicle,*** some portion of which ***might include ethanol***, might be present in an amount up to 90% by weight. Applicants submit that one of skill in the art would read claims 3 and 18 in light of the entirety of *Wain's* disclosure. Applicants submit that one of skill in the art would note the twelve examples provided in *Wain*, none of which have ***ethanol*** in an amount exceeding (or even reaching) 60%. *See Wain* at 11-16. Additionally, one of skill in the art would note *Wain's* statement that "the compositions [disclosed therein] ***will contain at most about 60% ethanol.***" Therefore, considering claims 3 and 18 in light of the entirety of *Wain*, one of skill in the art would not understand *Wain* to disclose ***at least about 70% by weight ethanol***.

Third, Applicants respectfully submit that the portion of *Wain* relied upon by the Final Office Action as disclosing ***at least about 70% by weight ethanol*** is not sufficiently specific to disclose this limitation. As noted in the MPEP 2131.03, prior art which teaches a range overlapping or touching the claimed range anticipates the claimed range if the prior art range discloses the claimed range with "***sufficient specificity***." MPEP 2131.03 notes:

> What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, and the reference teaches a broad range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims.

As noted above, *Wain* does not *specifically* disclose that the formulation comprises ***at least about 70% by weight ethanol***. Particularly, the Final Office Action relies upon a broad range (e.g., "up to 90% by weight") and a broad grouping of volatile vehicles (e.g., "acetone, isopropyl alcohol, methylene chloride, methyl-ethylketone, absolute alcohol, ethyl acetate, trichloromonofluoromethane (P11), or methylene dimethyl ether") as disclosing ***at least about***

70% by weight ethanol. Such broad disclosures are insufficient to disclose ***at least about 70% by weight ethanol*** with sufficient specificity.

A recent decision by the Federal Circuit in *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) clearly supports the proposition that *Wain's* broad disclosure of ***a volatile vehicle*** present in broadly-disclosed range of ***up to 90% by weight*** does not sufficiently specify ***at least about 70% by weight ethanol.*** In *Atofina*, the Federal Circuit held that a reference temperature range of 100-500 degrees C did not describe the claimed range of 330-450° C with sufficient specificity to be anticipatory. Further, even though there was a slight overlap between the reference's preferred range (150-350° C) and the claimed range, that overlap was not sufficient to anticipate.

Similarly, *Wain* fails to sufficiently specify ***at least about 70% by weight ethanol.*** Therefore, *Wain* cannot properly be cited as teaching this limitation. *Foldvari* is not cited as teaching this limitation. Thus, the combination of *Wain* and *Foldvari* does not contain each and every element of independent claim 1 and, as such cannot render obvious claim 1 or claims depending therefrom.

In consideration of the foregoing, Applicants respectfully request withdrawal of the rejections.

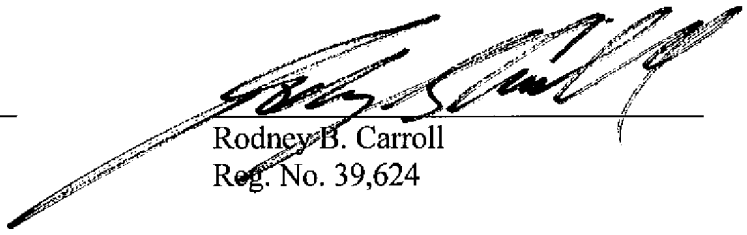
CONCLUSION

Consideration of the foregoing amendments and remarks, reconsideration of the application, and withdrawal of the rejections and objections is respectfully requested by the Applicants. No new matter is introduced by way of the amendment. It is believed that each ground of rejection raised in the Final Office Action dated April 30, 2010 has been fully addressed. If any fee is due as a result of the filing of this paper, please appropriately charge such fee to Deposit Account Number 50-1515 of Conley Rose, P.C., Texas. If a petition for extension of time is necessary in order for this paper to be deemed timely filed, please consider this a petition therefore.

If a telephone conference would facilitate the resolution of any issue or expedite the prosecution of the application, the Examiner is invited to contact the undersigned at the telephone number given below.

Respectfully submitted,

Date: 8-24-10



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